DETAILED ACTION

Acknowledgment of Papers Received: Remarks dated 10/29/09.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13, 15, 17, and 19-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Takaichi et al (USPN 5,455,235 hereafter '235). The claims are drawn to a composition comprising liposomed electrolytes. The claims are drawn also drawn to a method for orally rehydrating a subject comprising drinking the oral rehydration solution.

The '235 patent teaches an oral formulation comprising liposomed electrolytes (abstract). The formulation comprises electrolytes such as magnesium potassium and calcium salts (col. 4, lin. 20-35). The liposome includes soybean phospholipid (col. 6, lin. 40-45). The formulation has an osmolality from 200-270 mOsmols (col. 4, lin. 10-19). The formulation further comprises vitamins, flavors and amino acids (col. 5, lin. 35-40). Vitamins include vitamin E, C and retinol (col. 5, lin. 51-55, col. 7, lin. 25-30), amino acids such as sodium glutamine, glycine (col. 5, lin. 38) and flavors include grapefruit, orange lemon and pineapple (co. 5, lin. 35). The water content of the formulation is about 0.8% in a concentrated form (col. 10, lin. 10-18). The formulation is rehydrated with an amount of water and delivered to the subject (col. 8, lin. 60-67). The ingredients are combined and homogenized in order to arrive at the concentrated form (col. 7, lin. 55-60).

These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 10-12, 14, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Andon et al (USPN 5,468,506 hereafter '506). The claims are drawn to a composition comprising liposomed electrolytes and water, and a concentrated form of the composition.

The '506 patent discloses a composition comprising phospholipids, electrolytes, and a low concentration of water (abstract). The composition comprises phospholipids such as lecithin (col. 8, lin. 5) and electrolytes such as ionic calcium salts (col. 6, lin. 64-col. 7, lin. 13; col. 8, lin. 8-65). The water content of the formulation can be kept low, below 20% (col. 11, lin. 65-col. 12, lin. 28). This low water content provides a viscous syrup comprising high fructose corn

syrup having a Brix of 77 (col. 6, lin. 15-25). The formulation is homogenized (col. 11, lin. 65-col. 12, lin. 28).

The formulation differs from the instant claims in the water content. The '506 patent discloses a low water content of below 20%, while the instant claims have a water content below 10%. This is a result effective parameter that can be optimized through routine experimentation by those of ordinary skill in the art. The claims require the formulation to be concentrated, presumably removing the water content resulting in a viscous syrup with the resultant Brix value. The syrup of the '506 patent comprises a Brix of 77 and a low water content. It would have been prima facia obvious to lower the water content in order to further concentrate the syrup in order to reduce the size or increase the potency of the product. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention for the result effective variable of providing the desired cosmetic effect. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With these things in mind it would have been obvious to optimize the concentrations of the water in order to increase the potency of the dehydrated syrup. One of ordinary skill in the

art would have been motivated to optimize the water content with an expected result of a formulation useful as a drink or beverage base with a high potency that can be later diluted.

Response to Arguments

Applicant's arguments filed 10/29/09 have been fully considered but they are not persuasive. Applicant argues that:

The '235 patent does not anticipate the instant claims since it does not teach a composition comprising **an effective amount of liposomed electrolytes** as recited in the instant claims.

The '506 patent does not obviate the instant claims since it does not teach, disclose or suggest a composition comprising **an effective amount of liposomed electrolytes** as required by the instant claims.

Regarding the first argument it remains the position of the Examiner that the '235 patent continues to anticipate the instant claims. The instant claims recite a composition comprising electrolytes, liposome and water. The '235 patent discloses a composition comprising electrolytes (col. 4, lin. 20-37), liposome compounds (col. 6, lin. 41-44) and water (col. 10, lin. 5-40). Applicant argues that the electrolytes are not "liposomed" however this term is not defined by the claim. The specification indicates that the electrolytes are liposomed by blending the electrolytes with an aqueous solution of the liposome and homogenizing the resultant mixture at high pressure. The composition of the instant claims comprising water, electrolytes and liposome compounds are blended together and homogenized at high pressure (col. 7, lin. 55-60). The resulting homogenized formulation has an osmolality below 300 just as required by the instant claims. As such, the same compounds are combined and processed the same way,

resulting in the same formulation. Any concentration of electrolytes liposomed or otherwise present in the prior art formulation would be an effective amount absent a specified concentration. As such the prior art teaches each and every element of the claims and thereby anticipates the claims.

Regarding the second argument it remains the position of the Examiner that the '506 patent continues to obviate the instant claims. Applicant argues that that though electrolytes and liposomes are disclosed, the electrolytes are not disclosed as being encapsulated within the liposomes. However the claims do not recite this limitation. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., encapsulated electrolytes) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The composition of the '506 patent comprises electrolytes (col. 8, lin. 15-29), water (col. 7, lin. 40-50) and liposome compounds (col. 8, lin. 5). The compounds are mixed in an aqueous solution and processed at high shear and temperature in order to completely blend the mixture (col. col. 10, lin. 60-col. 11, lin. 65). As such the same compounds are combined in a similar way and as a result must have the same properties as the instant claims. The formulation has a similar Brix sweetness, and water content. Further since the claims do not explicitly claim any electrolyte concentration, any perceivable concentration of electrolytes, liposomed or otherwise would be an effective amount. For these reasons the claims remain obviated by the prior art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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